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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/795,931

Applicant(s)

JOHAL ET AL.

Examiner

David H. Kruse

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/8/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. § 119(e) or under 35 U.S.C. § 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119 as follows:

The later-filed application must be an application for a patent for an invention, which is also disclosed, in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. § 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/165,176, filed 12 November 1999, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. § 112 for one or more claims of this application. Provisional Application 60/165,176 fails to provide an adequate written description of SEQ ID NOs: 7, 8 or 9, to which all of the pending claims are directed. Hence, the instant application is only entitled to the priority date of 13 November 2000.

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Specification

2. The disclosure is objected to because of the following informalities: Parent Application 09/711,619 has issued as US Patent 6,750,380, page 1 of the specification should be amended to reflect this.

Appropriate correction is required.

Claim Objections

3. Claim 26 is objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically the recitation of an intended use, "used in commercial sorghum production", does not appear to further limit claim 25 from which claim 26 depends.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR § 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or

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patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR § 3.73(b).

5. Claim 1-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,750,380. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claimed in the '380 patent renders obvious the genus of isolated nucleic acids of the instant claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-27 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated nucleotide molecule having a nucleotide sequence encoding a P-glycoprotein that controls plant growth having at least 90% identity to the sequence of SEQ ID NO: 7 or 8, a complement of said nucleotide molecule, or a nucleotide molecule that hybridizes under specified

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stringent conditions to SEQ ID NO: 7 or 8. In addition, Applicant claims plants, plant cells and a method of modifying the growth of a plant comprising transforming a plant with said nucleotide molecule.

Applicant describes the sorghum Dw3 gene, exemplified in SEQ ID NOs: 7 and 8, encoding the polypeptide of SEQ ID NO: 9. Applicant also describes a mutation of said Dw3 gene that lead to dwarfing in sorghum having an 882bp duplication from exon 5 described on pages 49-50 of the specification, when present in a homozygous state in the sorghum plant (these examples are directed to a non-claimed invention).

Applicant does not sufficiently describe the genus of nucleotide molecules encoding a P-glycoprotein that controls plant growth having at least 90% identity to SEQ ID NOs: 7 and 8, other than those directed to a non-elected invention, or other nucleotide molecules that would hybridize under specified stringent conditions to a nucleotide molecule having the sequence of SEQ ID NO: 7 or 8. In particular, the genus of nucleotide molecules, that could be used in a method of modifying the growth of a plant that encode a P-glycoprotein that functions to control growth in said plant, is not adequately described.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that

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organism, despite the disclosure of a cDNA encoding that protein from another organism. The Federal Circuit has pointed out that under United States law, a description that does not render a claimed invention obvious cannot sufficiently describe the invention for the purposes of the written description requirement of 35 U.S.C. 112. *Eli Lilly*, 119 F.3d at 1567, 43 USPQ2d at 1405. See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. The art teaches the P-glycoproteins in plants have a wide variety of functions and are not specific to plant growth, wherein mutations would lead to a dwarf plant (see Martinoia *et al* 2002, *Planta* 214: 345-355). The Examiner notes that P-glycoproteins are also called ABC transporters or multidrug-resistance-related proteins in the art.

8. Claims 1-27 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 9, does not reasonably provide enablement for isolated nucleic acids having a nucleotide sequence at least 90% identical to SEQ ID NO: 7 or 8, or that hybridizes to said nucleotide sequences under the

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specified stringency conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims an isolated nucleotide molecule having a nucleotide sequence encoding a P-glycoprotein that controls plant growth having at least 90% identity to the sequence of SEQ ID NO: 7 or 8, a complement of said nucleotide molecule, or a nucleotide molecule that hybridizes under specified stringent conditions to SEQ ID NO: 7 or 8. In addition, Applicant claims plants, plant cells and a method of modifying the growth of a plant comprising transforming a plant with said nucleotide molecule.

Applicant teaches the sorghum Dw3 gene, exemplified in SEQ ID NOs: 7 and 8, encoding the polypeptide of SEQ ID NO: 9. Applicant also teaches a mutation of said Dw3 gene that lead to dwarfing in sorghum having an 882bp duplication from exon 5 taught on pages 49-50 of the specification, when present in a homozygous state in the sorghum plant (see page 4, 2nd paragraph of the specification; these examples are directed to a non-claimed invention). Applicant also teaches the P-glycoproteins influence traits in plants other than growth characteristics, such as pathogen resistance (see page 9, 2nd paragraph of the specification).

Applicant does not sufficiently teach the genus of nucleotide molecules encoding a P-glycoprotein that controls plant growth having at least 90% identity to SEQ ID NOs: 7 and 8, other than those directed to a non-elected invention, or other nucleotide molecules that would hybridize under specified stringent

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conditions to a nucleotide molecule having the sequence of SEQ ID NO: 7 or 8.

It is unclear from the instant teachings if the dwarfing mutations in the Dw3 gene would adequately teach how to make and use the invention within the claimed breadth. In particular, the genus of nucleotide molecules, that could be used in a method of modifying the growth of a plant that encode a P-glycoprotein that functions to control growth in said plant, is not adequately taught.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant only teaches a single species of the claimed genus of nucleic acid molecules. The art teaches the P-glycoproteins in plants have a wide variety of functions and are not specific to plant growth, wherein mutations would lead to a dwarf plant (see Martinoia *et al* 2002, Planta 214: 345-355). The Examiner notes that P-glycoproteins are also called ABC transporters or multidrug-resistance-related proteins in the art. Applicant does not teach what structures of the taught P-glycoprotein is critical for regulation of plant growth as required by the claimed invention. At the time of the instant invention, one of skill in the art could not predict the specific function of a P-glycoprotein based on the primary amino acid structure (see Martinoia *et al* 2002, page 353, under Conclusions).

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Hence, given the limited guidance by Applicant, the nature of the invention, and the relative skill of those in the art, it would have required undue trial and error experimentation by one of skill in the art to make and use the invention as broadly claimed.

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 21, 22, 25 and 26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21, 22, 25 and 26 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: wherein the nucleic acid molecule encoding the P-glycoprotein is in the antisense orientation. The invention of the instant claims appears to require suppression of an endogenous P-glycoprotein gene product in order to be operable, i.e. the height of said plant is reduced, and hence expression of an antisense transgene product would be essential.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-3, 5-7, 10-14, 17-22 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sidler *et al* 1998 (The Plant Cell 10:1623-1636) taken with the evidence of Fourgoux-Nicol *et al* (1999, Plant Molecular Biology 40: 857-872).

Sidler *et al* disclose an isolated nucleic acid encoding an ABC transporter (syn. P-glycoprotein) that controls plant growth that would hybridize under the conditions specified in the claims (see page 1633, left column, 2nd paragraph). Sidler *et al* disclose constructs using a constitutive CaMV 35S promoter operably linked to said nucleic acid in both the sense and antisense direction, and transformation of a dicot plant using said constructs. While Sidler *et al* disclose transforming the dicot *Arabidopsis thaliana*, the list of dicot species at claim 11 would have been considered to be function equivalents, especially the *Brassica* sp. Sidler *et al* disclose transformed seeds at page 1632, right column, last paragraph. Sidler *et al* disclose that expression of the antisense nucleic acid produced dwarfed plants under specific light conditions in Figure 5, page 1627, left column.

Fourgoux-Nicol *et al* teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65°C (page 859, left column, 2nd paragraph). Fourgoux-Nicol *et al* also teach that the probe and isolated DNA fragment exhibited a number of sequence differences

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comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). Hence, Fourgoux-Nicol *et al* teach that under stringent hybridization conditions, a wide variety of nucleic acids having low sequence similarity can be isolated. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same, material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the Applicant to provide that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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14. Claims 8, 9, 15, 16 and 23-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sidler *et al* 1998 (The Plant Cell 10:1623-1636) in view of Fourgoux-Nicol *et al* (1999, Plant Molecular Biology 40: 857-872).

The teachings of Sidler *et al* and Fourgoux-Nicol *et al* are outlined above.

Sidler *et al* do not teach transformation of monocot plants with a P-glycoprotein encoding nucleic acid that controls plant growth.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to isolate other P-glycoprotein encoding nucleic acids that controls plant growth and transform the homologous plant with an antisense to produce a dwarfed plant by modifying the teachings of Sidler *et al*.

Conclusion

15. Claim 4 is free of the prior art which neither teaches nor suggests P-glycoprotein encoding nucleic acids that controls plant growth that is at least 95% identical to the sequence set forth in either SEQ ID NO: 7 or SEQ ID NO: 8.

16. No claims are allowed.

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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

**DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER**



David H. Kruse, Ph.D.
12 July 2006

18. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.